K102927 (1/3)

2. 510(k) SUMMARY

JAN 2 6 2011

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, CA 95762

510(k) Contact: Matthew M. Hull, RAC
Phone: (916) 355-7156/ Fax: (916) 355-7190
mhull@consensusortho.com

Date Prepared: 30 September, 2010

Trade Name: Consensus® Knee System

Common Name: Porous-coated knee prosthesis for cemented or cementless use

Classification Name: Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis is a class II device per 21 CFR 888.3560 (Product Code JWH)

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3565 (Product Code MBH)

Review Panel: Orthopedic Devices

Device Description:
The Consensus Total Knee System (CKS) is a primary fixed-bearing total knee system that has been on the market since 1990's.

The CKS has been designed to replicate the natural anatomy of the knee in order to restore knee function. It has been developed to preserve and utilize healthy ligamentous structures. For cases where the soft tissues are not functional, the PCL substituting tibial inserts or the posterior stabilized system are available for increased stability.

The CKS incorporates femoral, tibial, and patellar components and all associated instrumentation needed for implantation. The CKS can be used for total knee replacement with posterior cruciate ligament (PCL) retaining or substituting.

The femoral components are provided in left and right side versions and are designed to replicate natural kinematic motion between the femur, tibia and patella. The Consensus femoral component is designed to provide uniform contact zones in the coronal plane throughout the range of motion when the knee is properly aligned. The femoral component is also designed with a large distal radius to optimize contact areas and reduce

contact stress. The trochlear groove in the femur is designed to allow the load from the patella to be evenly distributed on the femur with adequate lateral constraint.

Indications for Use:

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
D. The porous coated (CoCr beads with Titanium) femoral and tibial components may be used with or without cement.

Substantial Equivalence:

The CKS porous coated components that are the subject of this submission were previously cleared by FDA for cemented use in K001456 (femoral components) and K983004 (tibial components). This submission is to expand the indications to allow their uncemented use. The previous 510(k)'s for these devices were cleared prior to the change in our company's name from Hayes Medical, inc. to Consensus Orthopedics, Inc. in 2008. The CKS implants are also substantially equivalent to the following knee systems that are cleared for cementless use: Smith & Nephew's "ProFix Total Knee" (K051229 & K030623), Biomet's "AGC Total Knee" (K033489), and Zimmer's "Natural Knee" (K073286 & K070214).

Non-Clinical Performance Data:

Modified Surface Testing Specifications and Results:
The porous CoCr bead with Ti coating surface that is being indicated for cementless use is identical to the porous surface that was approved in K001456 and K983004. Below is a summary of the testing related to the porous coating.

Specification	Acceptance Criteria	Verification Results
Microstructure of the modified surface	N/A	Bead to Bead Neck Diameter 0.33 mm Pore Size 0.432 mm Volume % Porosity 37% Coating Thickness 0.889 mm
Corrosion of the modified surface shall be equal of less than that measured in a legally marketed device.	Equal to or improved corrosion resistance when compared with CoCr beads using ASTM F746 & G61	Critical Potential / Breakdown Potential CoCr Beads 1290 mV / 1200 mV Ti Coated CoCr Beads 1315 mV / 1200 mV
Modified surface shall exhibit adequate static tensile strength	The static tensile strength will exceed 20 MPa.	Static Tensile Strength of 58.32 MPa

Modified surface shall exhibit adequate static shear strength.	The static shear strength will exceed 20 MPa.	Static Shear Strength of 58.32 MPa
Modified surface shall exhibit adequate shear fatigue strength.	The shear fatigue strength will exceed 10 million cycles.	10 million cycles achieved with a strength of 13.78 MPa
Modified surface shall exhibit adequate rotating beam fatigue strength.	The rotating beam fatigue strength will exceed 10 million cycles.	10 million cycles achieved with a strength of 206.7 MPa
Modified surface shall not exhibit excessive abrasion.	N/A	200N load: Avg. mass loss 0.006 g Avg. thickness loss 6% 1500N load: Avg. Mass loss 0.179 g Avg. thickness loss 23%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.
% Mr. Matthew M. Hull, RAC
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

JAN 26 2011

Re: K102927
Trade/Device Name: Consensus® Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prothesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: January 18, 2011
Received: January 20, 2011

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102927

Device Name: Consensus® Knee System

Indications for Use:

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
D. The porous coated (CoCr beads with Titanium) femoral and tibial components may be used with or without cement.

Prescription Use ___X___ AND/OR Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102927